K121881

OCT 18 2012

510(k) SUMMARY

Domain Surgical System
Date of Summary: June 25, 2012

General Provisions

Submitter's Name:	Domain Surgical
Submitter's Address:	1370 South 2100 East Salt Lake City, Utah 84108
Contact Person:	Curtis Jensen, Vice President of Quality and Regulatory Affairs
Phone Number:	(801) 924-4958
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Proprietary Name:	Domain Surgical System
Common Name:	Electrosurgical cutting and coagulation device and accessories

Name of Predicate Device(s)

- Domain Surgical System (Product Code GEI) 510(k) #K110439
- Peak Surgery System (Product Code GEI) 510(k) #K082786.

Intent of This Premarket Submission

The intent of this submission is to modify the Indications for Use statement to add specificity, consistent with our intended use for the device and the indications for use for the legally marketed Peak Surgery System (K082786).

The Domain Surgical System, as presented in this submission, has been previously cleared by FDA through 510(k) #K110439.

Device Description

The Domain Surgical System is identical to the device cleared by FDA in 510(k) #K110439.

An electrosurgical cutting and coagulation device (and accessories) is a device intended to remove tissue and control bleeding by use of high-frequency electrical current (21 CFR §878.4400). It is classified as a Class II (510(k)) device.

The Domain Surgical System is a soft tissue cutting and coagulation device that consists of a generator that is electrically connected to a sterile, single-use handpiece and an optional footswitch. Like the predicate devices, the handpiece includes an actuation button that can be used to activate heating in the handpiece tip. Also like the predicate devices, an optional footswitch can be used to activate the system.

Technological Comparison

The technological characteristics are the same as the predicate device (Domain Surgical System) as described in K110439 and the difference between the Domain Surgical System and the Peak Surgery System are no more significant that the differences between the Domain Surgical System and the predicate device cited in K110439.

Indications for Use

The Domain Surgical System is indicated for cutting and coagulation of soft tissue during surgical procedures, including Gynecologic procedures (open transabdominal only).

The proposed indications for use statement for the Domain Surgical System references a subset of the surgical specialties to add specificity, consistent with our intended use for the device and the indications for use for the legally marketed Peak Surgery System (K082786).

Safety and Biocompatibility Summary

The Domain Surgical System, as originally cleared in 510(k) #K110439, is intended to be used by surgeons independent of medical specialty. This premarket submission is to modify the indications for use for the Domain Surgical System to provide specificity, consistent with our intended use for the device and the indications for use for the legally marketed Peak Surgery System.

Questions of safety and effectiveness of the Domain Surgical System were assessed during the review and clearance of the original 510(k) (#K110439).

Bench testing was performed with the Domain Surgical System to assure that it functioned as intended. Bench tests verified that the generator output was within specification and that the thermal output of the handpiece tip corresponded to the target values. It was also tested by an accredited independent testing laboratory to assure that it complies with the applicable electrical safety standards for medical electrosurgical devices, including the applicable sections of IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-2-2. All of this testing was previously reported as part of 510(k) #K110439.

The software that controls the operation of the generator has previously undergone proper design verification and validation to assure that it meets design requirements and operates safely and effectively for the device's intended use, including controlling output power and providing audio and visual information during use. All of this testing was previously reported as part of 510(k) #K110439.

The patient contacting materials used in the Domain Surgical System were chosen for their biocompatibility, function and suitability for the intended use of this device. Successful biocompatibility testing of applicable parts of the system was completed by accredited independent testing laboratories according to ISO 10993-1 and 510(k) Memorandum G95-1. All of this testing was previously reported as part of 510(k) #K110439.

Conclusion

The technological characteristics are identical to the device described in K110439 and the difference between the Domain Surgical System and the Peak Surgery System are no more significant that the differences between the Domain Surgical System and the predicate device cited in K110439.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 18 2012

Mr. Curtis Jensen
Vice President of Quality and Regulatory Affairs
Domain Surgical, Inc.
1370 South 2100 East
SALT LAKE CITY UT 84108

Re: K121881
Trade/Device Name: Domain Surgical System
Regulation Number: 21 CFR§ 884.4120
Regulation Name: Gynecologic electrocautery and accessories
Regulatory Class: II
Product Code: HGI
Dated: September 18, 2012
Received: September 24, 2012

Dear Mr. Jensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121881

Device Name: Domain Surgical System

Indications for Use: The Domain Surgical System is indicated for cutting and coagulation of soft tissue during surgical procedures, including Gynecologic procedures (open transabdominal only).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: _____ (21 CFR 801 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121881